



DEPARTMENT OF HEALTH AND HUMAN SERVICES

95090d

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 758-7118
FAX: (612) 334-4142

November 15, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 05 - 03

Hillel S. Roberts
President
Upscale Foods, Inc.
4630 Quebec Avenue North
New Hope, Minnesota 55428

Dear Mr. Roberts:

I am writing in reference to an inspection of your establishment located at 4630 Quebec Avenue North, New Hope, Minnesota, on March 29 and April 1, 2004. Copies of labels for several of your food products were collected for review during the inspection. The labels cause your products to be misbranded under Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and food labeling regulations, Title 21 of the Code of Federal Regulations (CFR), Part 101, on FDA's Internet website at www.fda.gov.

THE OLD CITY CAFÉ MACARONI & CHEESE DINNER

Your product "the Old City Café Macaroni & Cheese Dinner" is misbranded under Section 403(e) of the Act in that the label does not bear the correct location of the manufacturer, packer, or distributor, as required by 21 CFR 101.5(d).

THE OLD CITY CAFÉ VEGETARIAN BEEF AND BEAN BURRITO

Your product "the Old City Café Vegetarian Beef & Bean Burrito" is misbranded under Section 403(a)(1) of the Act in that the label includes the word "beef" in the statement of identity; however, beef is not used in this product, and therefore the use of the term is false and misleading.

In addition, your Old City Café Vegetarian Beef & Bean Burrito is misbranded under Section 403(i)(2) of the Act in that the ingredient statement on the product label fails to declare all of the ingredients in the product by their common or usual names, as required by 21 CFR 101.4(a) and (b). For example:

Page Two

Hillel S. Roberts
November 15, 2004

- According to documents you provided to the investigator during the inspection, the textured vegetable protein used in the manufacture of this product contained caramel coloring. However, the ingredient statement does not list the caramel coloring. [See 21 CFR 101.4(b)(1), 101.22(k).]
- The beans and food starch used in the burrito are not declared by their common or usual names in that the type or variety of beans and food starch used in the burrito are not specified.
- Your product label declares "organic evaporated cane juice" in the ingredient list; however, the common or usual name for this ingredient is sugar.
- The tomato paste used in the burrito is made from two or more ingredients, and the baking powder is also made from two or more ingredients, but the sub-ingredients in the tomato paste and baking powder are not included in the ingredient list. [See 21 CFR 101.4(b)(2).]

THE OLD CITY CAFÉ NEW YORK STYLE CHEESE PIZZA

Your product "the Old City Café New York Style Cheese Pizza" is misbranded under Section 403(i)(2) of the Act in that the ingredient statement on the product label fails to declare all of the ingredients in the product by their common or usual names, as required by 21 CFR 101.4(a) and (b). For example, the skim milk mozzarella cheese used in the manufacturing of the pizza is made from two or more ingredients, but those sub-ingredients are not declared in the ingredient list. [See 21 CFR 101.4(b)(2).] Furthermore, your product label declares "organic evaporated cane juice" in the ingredient list; however, the common or usual name for this ingredient is sugar.

Furthermore, your product is misbranded under Section 403(q)(1)(A)(i) and (q)(1)(B) because the serving size and servings per container on the Nutrition Facts panel are not declared in accordance with the requirements for serving size. According to your label, the serving size of your product is 85g. However, the reference amount customarily consumed for pizza is 140g (see 21 CFR 101.12, Table 2, under "mixed dishes"). The serving size and nutrition information for this product must be based on the reference amount of 140g, and the serving size must be expressed as the fractional slice of the product that most closely approximates the reference amount (e.g., "1/3 pizza"). [See 21 CFR 101.9(b)(2)(ii)].

THE OLD CITY CAFÉ CHEESE ENCHILADA

Your product "the Old City Café Cheese Enchilada" is misbranded under Section 403(i)(2) of the Act, in that the ingredient statement on the product

Page Three

Hillel S. Roberts
November 15, 2004

label fails to declare all of the ingredients in the product by their common or usual names, as required by 21 CFR 101.4(a) and (b). For example, the part skim milk mozzarella, cheddar cheese, and baking powder used in the cheese enchilada are made from two or more ingredients, but those sub-ingredients are not declared in the ingredient list. [See 21 CFR 101.4(b)(2).]

THE OLD CITY CAFÉ BEAN & CHEESE BURRITO

Your product "the Old City Café Bean & Cheese Burrito" is misbranded under Section 403(i)(2) of Act in that the ingredient statement fails to declare all of the ingredients in the product by their common or usual names, as required by 21 CFR 101.4(a) and (b). For example, the beans and the food starch used in the bean and cheese burrito are not declared by their common or usual names in that the type or variety of beans and food starch used in the burrito are not specified. Furthermore, the tomato paste and cheese are made from two or more ingredients, but those sub-ingredients are not declared in the ingredient list. [See 21 CFR 101.4(b).]

This letter is not intended to be an all-inclusive list of the deficiencies in your products and their labeling. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations. You should review the labeling for all of your products to assure that it is in compliance. We may take regulatory action without further notice if you do not promptly correct these violations. For instance, we may seize your products and/or enjoin your firm from operating.


Please notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. Copies of the revised labeling should also be submitted. If corrective action cannot be completed within 15 working days, state the reason(s) for delay and the time at which the corrections will be completed.

You should direct your reply to John Quaife, Compliance Officer, at the address indicated in the letterhead. If you have any questions concerning this letter, please contact Mr. Quaife at (612) 758-7117.

Sincerely,



W. Charles Becoat
Director
Minneapolis District


JTQ/ccl